



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,657	02/08/2002	Srinivasan Ramanathan	2560-1-001 N	3296

23280 7590 12/29/2004

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 SEVENTH AVENUE, 14TH FLOOR
NEW YORK, NY 10018

EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	10/072,657	Applicant(s)	RAMANATHAN ET AL.
Examiner	Maury Audet	Art Unit	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 October 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 69-91,93 and 96-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 69-91,93 and 96-107 is/are rejected.
- 7) Claim(s) 70 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 07/18/02.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

Applicant's amendment and response of October 04, 2004 is acknowledged. Claims 69-91,93 and 96-107 are pending. It is noted that the elected invention is the conjugation of 3 compounds: 1. a polymer; 2. a cellular uptake promoter, and 3. the therapeutic agents of peptide SEQ ID NOS: 1-8.

Claim Objections

Claim 70 is objected to because of the following informalities: the opening "The polymer" should be "The method of claim 69, wherein the polymer comprises . . .", as consistent with method of use subject matter of the invention and the remaining dependent claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd

The rejection of claims 69-91,93 and 96-107 under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention, is maintained for the reasons of record. Applicant's arguments have been fully considered but are not persuasive. The **elected invention** is drawn to a polymer conjugated to a cellular uptake promoter and **the therapeutic agents of peptide SEQ ID NOS: 1-8 (i.e. claim 107)**. The claims still read upon any "therapeutic agent or diagnostic agent" (which SEQ ID NOS: 1-8 are not deemed to be as well, absent evidence to the contrary that they may dually function as therapeutic agents or diagnostic agents, see i.e. claim 107). It is suggested that Applicant amend

claim 69 to delete the phrase "or diagnostic agent" and limit the therapeutic agents to SEQ ID NOS: 1-8 (notwithstanding other rejections herein).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 69-91,93 and 96-107 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/47173 (University of Medicine and Dentistry of New Jersey).

WO 99/47173 (previously cited as prior art of record) teaches a method of delivering a therapeutic agent from an initial bodily compartment to at least one target bodily compartment using a conjugate of 1. a polymer (i.e. PEG), 2. a cellular uptake promoter (i.e. biotin), and 3. the therapeutic agents of SEQ ID NOS: 1-8 (see i.e. claims 1, 4, and 20, entire document).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 69-91,93 and 96-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/47173 (University of Medicine and Dentistry of New Jersey).

WO 99/47173 is discussed above.

It would have been obvious to one of ordinary skill in the art at the time of the invention, if not expressly disclosed therein, to use any polymer or any cellular uptake promotor in the conjugate of the method of delivering a therapeutic agent from an initial bodily compartment to at least one target bodily compartment of WO 99/47173, because the advantageous use of other related polymers or cellular uptake promoters (which Applicant maintains as broadly claimed) using the same elected therapeutic agents (SEQ ID NOS: 1-8) is merely a matter of judicious selection by one of skill in the art, absent evidence to the contrary.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment (and clarification of the invention to the point that prior art could be applied) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1654

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 12/27/04



CHRISTOPHER R. TATE
PRIMARY EXAMINER